

## **REMARKS**

Claims 32-54 are pending, with claims 32 and 41 being the independent claims.  
By this Amendment, claims 32 and 41 have been amended.

Reconsideration based on the following remarks is respectfully requested.

### **I. The Drawings Satisfy All Formal Requirements**

The Office Action objects to the drawings based on informalities. Specifically, the Office Action indicates that the drawings fail to show “element 200” and element 210 as shown in FIG. 7 is not described in the specification. These objections are respectfully traversed.

Element 200 is shown in FIG. 6D, and element 210 does not appear anywhere in the figures.

Withdrawal of the objection to the figures is respectfully requested.

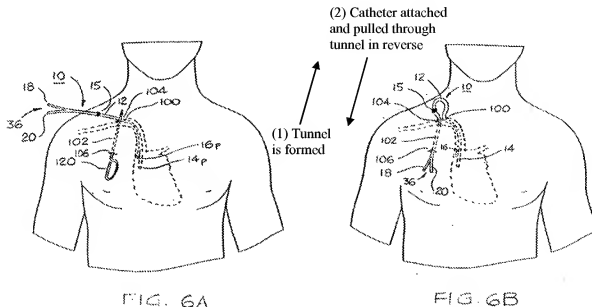
### **II. The Claims Define Patentable Subject Matter**

The Office Action rejects claims 32-39 and 41-54 under 35 U.S.C. 103(a) over Schon (U.S. Patent No. 6,682,519) or Markel et al. (U.S. Patent No. 5,624,413) in view of Pourchez (U.S. Patent No. 6,001,079); and claims 43 and 46 under 35 U.S.C. 103(a) over Schon or Markel in view of Pourchez, and further in view of Smith, III (U.S. Patent No. 4,832,687). These rejections are respectfully traversed.

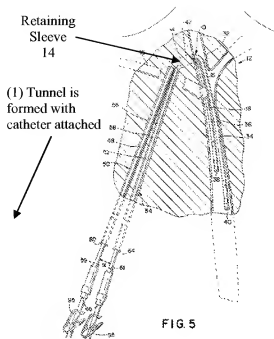
Neither Schon nor Markel disclose or suggest a method for surgically implanting a multi-lumen catheter including a step in which “after the subcutaneous tunnel is completely formed, guiding ... at least a portion of the multi-lumen tube portion through the subcutaneous tunnel”, as recited in independent claims 32 and 41.

As shown in FIG. 6A-B of the Present Application (reproduced below), the insertion method includes inserting the proximal tips 14p, 16p of the catheter 10 into the desired location within the patient using a standard technique, such as the Seldinger technique, and then reverse tunneling the distal end 36 of the catheter 10 through one subcutaneous tunnel 102. For example, after the tips of the catheter 10 are placed in the patient's body, a subcutaneous tunnel 102 is formed by a trocar beginning at a remote

location and moving towards the location of the incision from which the catheter extends. After the trocar has created the subcutaneous tunnel 102, the distal end 36 of the catheter 10 is attached to the trocar and pulled back through the tunnel 102 away from incision.



In contrast, the insertion method in Schon discloses inserting the tips of catheters into a vein 32, such as using a standard Seldinger technique, and then forward tunneling the two catheters in separate subcutaneous tunnels. For example, after the tips of each of the two catheters are placed in the patient's body, the end of the first catheter 16 extending from the patient's body is attached to a tunneling device. The tunneling device, with the catheter attached, is then forced forward through a subcutaneous tissue of the patient, forming a tunnel 56 using a tunneling device which attaches to the proximal end 59 of the first proximal portion 48 of the first catheter 16 while pulling the catheter 16 through the tunnel. The disclosure of Schon with respect to tunneling of the catheters subcutaneously is essentially limited to col. 11, lines 2-15. Thus, to the extent that Schon makes any particular disclosure as to tunneling of catheters, it discloses only forward tunneling. That is, the catheter is attached to the trocar before any tunnel exists and the trocar simultaneously excavates a subcutaneous tunnel while threading the catheter through the tunnel.



Similarly, Markel discloses a method of inserting a multiple catheter assembly in which the catheter assembly is first inserted into the catheterization area, and then the assembly is secured to a fixed source or location in or on the body, such as a subcutaneous area in the body. See col. 3, lines 35-46 and FIG. 3 of Markel. Securing the assembly to the subcutaneous area of the body is accomplished by a tunneling procedure through an incision. See col. 7, line 66 - col. 8, line 8 of Markel. However, Markel does not disclose that the catheter assembly is inserted through the tunnel after the tunnel is completely formed, but rather suggests that the tunnel is formed while the catheter assembly is being inserted through the tunnel. Thus, Markel suggests a forward tunneling procedure, rather than the reverse tunneling procedure of the claimed invention.

For at least these reasons, it is respectfully submitted that independent claims 32 and 41 are in condition for allowance. The dependent claims are also allowable for the reasons discussed as well as for the additional features they recite. Applicants respectfully request that a timely Notice of Allowance be issued in this case.

The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 01-1785.

Respectfully submitted,

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Dated: New York, New York  
December 22, 2009

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